

REMARKS

Claims 1-18, 20-21, and 23-33 are currently pending. Applicants reserve the right to pursue the subject matter of these canceled claims at a later date.

Rejections Under 35 U.S.C. §103

Claims 1-8, 14-18, 20, 21, and 23-31

Claims 1-8, 14-18, 20, 21, and 23-31 are rejected as being unpatentable over Kuipers I in view of Domanico since allegedly it would have been obvious to use a zwitterionic detergent in the putative method of Kuipers I. See Office Action at pages 3-6.

In Response to Arguments, Examiner asserts that it would be obvious to substitute of a zwitterionic detergent for a nonionic detergent, and to evaluate the combination of zwitterionic detergent and nonionic detergents in cell lysis procedures. However, applicant would like to point out in the application that "[M]ost nonionic detergents, such as Triton X, Tween 20 and NP-40, are less effective than the ionic detergents at disrupting protein aggregates" (page 3, last sentence of second paragraph). Here, the applicant uses zwitterionic compounds which possess some properties of ionic detergents and some properties of non-ionic detergents, and it functions differently from the nonionic detergents.

Further, Examiner states that Domanico teaches that the use of zwitterionic and non-ionic detergents can be alternated. This is not the case here. The present application is directed to a specific different result between using zwitterionic compounds and using nonionic compounds [Figure 2].

Examiner also noted that the in Figure 2 and Example 1 combination of a zwitterionic detergent and a chaotrope does not result in precipitation (OA page 9, second paragraph). Figure 2 illustrates that combination of zwitterionic and chaotrope precipitates DNA (recovers DNA) much better than the combination of non-ionic zwitterionic and chaotrope detergents.

In Office Action page 9, third paragraph, Examiner states that Domanico reference would allow isolation of either or both high and low molecular weight nucleic acids. Examiner further stated that applicant is arguing limitations that are not in the claims. Applicant respectfully disagrees. The purpose of the argument is to show that the present invention directs to a different result than the prior art that Domanico taught, since Domanico teaches the isolation of low molecular weight DNAs. Therefore, Domnaico will not render the present invention obvious.

In conclusion, substituting the nonionic detergent in Kuiper's method with zwitterionic detergent taught by Domanico will not make Kuiper's method work. Applicants assert that the Office has not established a prima facie case of obviousness. Thus, withdrawal of the rejection is respectfully requested.

Claims 9-13

At page 10 in Office Action, Examiner asserts that applicant admitted "that one could have been motivated to omit the extraction step in order to save time and reagent." The allegation is false. Applicant merely re-iterated Examiner's rejection and it does not constitute an admission. Moreover, Applicant maintains the arguments that Examiner failed to provide motivation for omitting the extraction step. It is a hindsight statement by suggestion of "saving time and reagents" to skip the organic extraction step. There is no suggestion in the primary references for such combination and one of the skilled in the art will not be motivated to apply the material to the solid phase without the instant invention. Omitting steps here not just merely save time, it also ensure at least the same quality of the sample preparation. Therefore, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 21 and 23-31

With respect to kit claims 21 and 23-31, the Examiner asserts that it would have been obvious to create a kit comprising the elements Kuipers I, as modified by Domanico. See Office Action at page 6. Applicants respectfully traverse this rejection.

None of pending Claims 21 and 23-31 includes phenol/chloroform, ethanol, or chloroform, in contrast to the alleged teachings of Methods 3b, 3c, 4b, and 4c of Kuipers I, cited by the Examiner. See Office Action at page 3. Applicants respectfully assert that the person of skill in the art would not be motivated to combine the components of the cited methods of Kuipers I, including organic one or more organic solvents, even as modified by Domanico, to obtain the Applicants kits. Further, other than an unsubstantiated assertion, the Examiner has provided no evidence that the person of ordinary skill would be motivated to assemble a kit comprising the experimental reagents of Kuipers I and/or Domanico. For at least these reasons, Applicants believe that this rejection is improper and request that the Examiner withdraw the rejection.

Claims 21 and 23-31 are rejected as allegedly being unpatentable over Domanico. See Office Action at pages 6. The Examiner contends that Domanico taught a method for isolating nucleic acid using a lysis solution comprising guanidine hydrochloride, guanidine thiocyanate, N-decyl-N,N-dimethyl-3-ammonio-1-propanesulfonate and binding the nucleic acid to a solid matrix. See Office Action at page 6. The kit of claim 21 comprises at least one protease. Applicants respectfully assert that Domanico neither teaches or suggests the use of one or more protease in the lysis solution, thus the kit of Claim 21 is not rendered obvious by the alleged teachings of Domanico. Claims 23-31 depend on claim 21, either directly or indirectly. In light of the foregoing, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 32 and 33

Claims 32 and 33 are alleged unpatentable over Kuipers I and Domanico, as the Examiner has applied these two references to claims above. The Examiner further relies on Kuipers et al. (Arthritis and Rheumatism (1998 Oct) Vol. 41, No. 10, pp. 1894-5) ("Kuipers II") because, the Examiner asserts, Kuipers II taught detecting Chlamydia gDNA from peripheral blood leukocytes. Applicants respectfully traverse this rejection.

As noted above, the combination of Kuipers I and Domanico does not teach or suggest "exposing the combination" to at least one solid phase. Rather, the alleged methods of Kuipers I cited by the Examiner each comprise an

intermediate organic extraction step. This deficiency is not overcome by Kuipers II. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Examiner stated that "[A]pplicant appears to argue that organizing experimental reagents prior to use is not standard laboratory practice that reduces the frequency of error." The issue for this instant application is not the organization of experimental reagents for standard laboratory practice. The issue here is to make the extraction of DNA more efficient in quality and quantity with fewer steps involved.

Obviousness-type Double Patenting Rejections

Claims 1-3, 5-12, 14, 15, 17-19, and 21-30 are rejected as allegedly being unpatentable over claims 1-64 of U.S. Patent No. 6,762,027 (the '027 patent). Applicants respectfully request that this rejection be held in abeyance until patentable subject matter has been identified.

CONCLUSION

Applicants believe that the application is now in condition for allowance and respectfully request issuance of a Notice of Allowance. If the Examiner does not consider the application to be in condition for allowance, Applicants request that he call the undersigned at (760) 931-6676 to set up an interview.

Respectfully submitted,

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